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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ERIC J. BENJAMIN, REINHARDT B. BAUDY and
MICHAEL R. BRANDT

Appeal 2009-008378
Application 10/820,215
Group Art Unit 1600

Oral Hearing Held: February 2, 2010

Before TONI R. SCHEINER, DONALD E. ADAMS, and
LORA M. GREEN, *Administrative Patent Judges*

ON BEHALF OF THE APPELLANTS:

MICHAEL J. MORAN, ESQ.
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THE CLERK: Good morning. Calendar number 7, appeal number 2009-008378, Mr. Silver.

JUDGE SCHEINER: Thank you. Good morning.

MR. SILVER: Good morning.

JUDGE SCHEINER: Okay. And you are Mr. Moran?

MR. MORAN: I am. Do I –

JUDGE SCHEINER: Okay. Yes, wherever you like. Here is the -- we have two names here, for the record. Can we move that out of your way for you?

MR. MORAN: I'm fine.

JUDGE SCHEINER: Okay. Good morning.

MR. SILVER: Good morning. I am Joel Silver. This is Michael Moran, representing Wyeth.

JUDGE SCHEINER: Okay.

MR. SILVER: I would like to thank the Board for taking -- giving us the opportunity to present this case.

So, kind of just to give you an introduction on the case, a brief layout, the compound, the phosphonic, a phosphonic acid compound, is a known NMDA antagonist. However, what the invention is directed to is a novel intra nasal administration method.

So, what we have shown is that the compound is more efficacious, tenfold more so than the oral administration method, and equivalent in -- to the IP, or intraperitoneal, administration method.

The claims -- currently Claims 1 through 9 and Claims 26 through 41 -- are rejected under 112, as well as Claims 10 through 23 and 42 through 56. There is also a 102 rejection. I would like to start with the 112 rejection.

JUDGE SCHEINER: Okay.

MR. SILVER: The Claims 1 through 9 and 26 through 41 are pharmaceutical composition claims. They are rejected as being directed to pharmaceutical compositions for treatment of any and all diseases and/or conditions associated with amino acid receptor activity. But the claims do not recite a specific indication.

So, it appears the Examiner is reading a method of treatment into the pharmaceutical composition claim –

JUDGE GREEN: But didn't the Examiner make one ground o f rejection over all the claims, Claims 1 through 56?

MR. SILVER: Yes. But –

JUDGE GREEN: Now, did you argue the composition claims separately from the method claims in your Appeal Brief? Because I would like to see where you did that.

MR. SILVER: The -- in the Reply Brief?

JUDGE GREEN: No, the Appeal Brief.

(Pause.)

MR. SILVER: So, in the -- on page 12, the pharmaceutical composition claims meet the enablement requirements under 112. Do you have that?

JUDGE GREEN: Right.

MR. SILVER: First paragraph, "Appellants have described detail to enable a skilled person to use the intra nasal composition" --

JUDGE GREEN: But you do not even point out what claims are, the composition claims, right?

MR. SILVER: In the Appeal Brief?

JUDGE GREEN: Or in the Reply Brief.

MR. SILVER: In the Reply Brief they are pointed out on –

(Pause.)

MR. SILVER: The claims aren't split out –

JUDGE GREEN: So, I mean, you have not said anywhere that the claims do not stand all together. You do not tell me what groups are -- what claims are in the two different groups. How am I supposed -- you want me to treat this as separate -- the compositions separately from the methods?

MR. SILVER: I would like to consider the different standards of the pharmaceutical composition claims –

JUDGE GREEN: I understand that there are different standards. And I have no issues with that.

MR. SILVER: Okay.

JUDGE GREEN: My issue is you have just kind of done this gloss, saying that -- the composition and then the method, but you have not come out, pulled out claims, said whey they are separately patentable, or anything else.

The only thing your heading says is Claims 1 through 56 are enabled. To me, that means that you are arguing all the claims together. So, I am asking you why I should consider them separately.

MR. SILVER: I think I agree that they are not split out with respect to the -- the arguments don't specify which claims in our pharmaceutical composition versus method. I think the arguments are split with respect to the treatments in the pharmaceutical composition.

If I can then direct to the method of treatment arguments, as well, the -- as I said, the compound isn't a known NMDA antagonist. And basically, the invention sets forth a more efficacious administration method.

And the NMDA target is a well-known target for treating a number of different diseases.

JUDGE GREEN: But -- it is a well-known target, but it -- I mean the art that you have brought in is saying how hard this is to target, therapeutically. Like, one of the references -- I think it is the Bergink reference -- says that NMDA receptor antagonism is not a valid therapeutic approach for the treatment of anxiety disorders. And that is the paragraph bridging 180 to 181.

The Wood reference at page 231, "NMDA receptor modulators will probably never be effective treatments for stroke," and it seems to be due -- because these things are involved in so many things.

MR. SILVER: Right.

JUDGE GREEN: How do you target this without getting this, and get all these other CNS side effects and everything?

And I do not think your specifications addressed any of that. And your specification says you were going to treat all of this. So I am really having a hard time with the methods, given the art that you provided me, to say, "Hey, these are enabled."

MR. SILVER: Okay. Yes, so the treatment methods -- this does have -- the CNS or the NMDA receptor is targeting a number of different disorders, and I think the Wood reference does point that out.

JUDGE GREEN: But they are saying that it is so -- it's everywhere that this is involved in, that you cannot -- it's very hard to target the condition you want to target, having all these other side effects.

MR. SILVER: And I think that has been a complication of some of the compounds.

JUDGE GREEN: But you have not shown me that your compound -- or any evidence that your compound does not hit any of these, have any of these other side effects. And you want to treat stroke, you want to treat schizophrenia, you want to treat anxiety, you want to -- I mean you want to treat basically anything that an NMDA receptor is involved with.

So, I am having a hard time seeing how your method claims are enabled, given that you have one model, and that is the tail model with the mouse. And even your art that you brought in says there are issues with this model, because they are not sure if it is due to the activity of the compound, or something else that is going on. So –

MR. SILVER: And I think that side effects are a concern that -- and when these references are referring to issues with compounds going forward with the FDA, they will link to the first stage of the FDA trials, which is the safety studies. I think, for patentability, the standard is not the same as under the FDA for regulatory –

JUDGE GREEN: I understand that. But you have to have an enablement that one of ordinary skill in the art will believe. And what we have is what -- you have to have an art accepted model and an art accepted correlation. From what I gather from the art that you submitted, there does not seem to be any art accepted model or art accepted correlation. So that is where the disconnect is.

I agree, we do not have to follow the FDA standards. But we do have something that one of ordinary skill in the art would understand may have a correlation to clinical efficacy. And I do not see that, especially given the references that you cited to me to say, "These are enabled." All these references are saying this is never going to work here, this is never

going to work here. The models that we do have do not seem to correlate very well.

And you have not even focused on one particular disease, or one particular -- that this may actually work very well in. You have just thrown them all in there. So, how do I pick and choose? I cannot –

MR. SILVER: Well, I think with respect to the hypersensitivity model does correlate to -- it's basically a stimulant, a pain –

JUDGE GREEN: But we are not limited to pain. I mean you are claiming everything in your method claims.

MR. SILVER: Well, just with respect to Claim 21 –

JUDGE GREEN: But you have not argued those separately. Then we are back to that again. I mean at best, you may have argued the compositions differently from the methods. And I am not sure that you have done that. I am going to have to go back and relook.

MR. SILVER: Okay.

JUDGE GREEN: Under our rules, you have not. Under our rules, you are supposed to have separate headings, and list the claims, and everything else. You have not done any of that.

But even then, at best, those might be the two groups you get. And I am not even saying that I can pull those two groups out. But the method claims, I am not going to start pulling the pain method from the anxiety from the schizophrenia, from everything else, because you haven't argued any of those separately. And you haven't pointed me out to what claims that those particular disorders go to, or anything else.

So, there is a little bit of a burden here on your part to tell me what claims we are talking about, and why it should be separately patentable, given the rejection.

MR. SILVER: I specifically identified the –

JUDGE GREEN: Yes, and if you look at our rules, that is what it says to do.

MR. SILVER: Sure, right.

JUDGE GREEN: To have separate headings –

MR. SILVER: Yes.

JUDGE GREEN: -- with different claim numbers, and everything else. So –

MR. SILVER: Should we move on to the 102 –

JUDGE GREEN: Yes, please.

MR. SILVER: So, the current 102 rejection is over Lynn. Lynn is directed to rapamycin administration, in conjunction with other agents. Lynn is not directed to an intra nasal administration.

JUDGE GREEN: Well, Lynn does say you can do -- use an intra nasal administration.

MR. SILVER: Yes, yes, absolutely. So Lynn does disclose that you can administer rapamycin intranasally. The issue is that Lynn doesn't disclose what we are claiming, which is the intra nasal administration for phosphonic acid.

JUDGE GREEN: But if we look at Claim 1, which is drawn to the composition -- correct?

MR. SILVER: Yes.

JUDGE GREEN: Our Claim 1?

JUDGE GREEN: Wait, I -- yes. Pharmaceutical composition for intra nasal administration, yes. So it is a composition?

MR. SILVER: Mm-hmm.

JUDGE GREEN: Okay. And in your specification, you define intra nasal, what is required for it, very generally. Like, "All you really need is a lipid carrier, and then maybe some other excipients or anything else," but really, you do not require much for intra nasal administration in your -- for the composition itself.

MR. SILVER: Yes, an intra nasal –

JUDGE GREEN: But to me, intra nasal could read on this compound and saline, correct?

MR. SILVER: Correct.

JUDGE GREEN: So -- and then Lynn teaches the rapamycin -- if you look at lines -- let me see, I think it is 23, 24, and 25 on page 3 of Lynn. "This invention provides a pharmaceutical composition comprising rapamycin and an NMDA antagonist in a pharmaceutically acceptable carrier," which could be saline. And your comprising language does not exclude the rapamycin.

MR. SILVER: Well, with the -- where Lynn does disclose the intranasally –

JUDGE GREEN: But -- I understand that, but your Claim 1 is a composition claim. It does not require -- all it has to be is suitable for intra nasal administration, which could be a saline solution.

MR. SILVER: Right.

JUDGE GREEN: So, when we look at the composition, here we have a composition comprising one of your compounds that -- of your claim compounds, rapamycin, and a pharmaceutically acceptable carrier, which they teach could be -- you know, I think they specifically teach one that is water and a buffer.

MR. SILVER: Well, it –

JUDGE GREEN: So they say the pharmaceutical carrier may be a liquid, such as water, Tween 80, and phosphocel or phosphogel PG-50. That is at page six, I think -- the line bridging pages six and seven.

Well, they call it an oral formulation. Why wouldn't that be suitable for intra nasal administration, given the broad definition of that kind of composition that you have in your specification?

MR. SILVER: Well, again, that is a carrier for rapamycin.

JUDGE GREEN: But they teach -- they specifically teach -- a composition comprising rapamycin and NMDA antagonists in a pharmaceutically acceptable carrier, and they are saying this is a pharmaceutically acceptable carrier.

MR. SILVER: Right. The -- well, I guess what I was saying is the specific -- when you take the two elements and you combine them into that, the NMDA – our specific compound is listed in a list of different agents that can be potentially combined.

JUDGE GREEN: But it is not a huge list, and it is specifically listed. I mean we have the species listed; we do not have a genus listed.

MR. SILVER: Right.

JUDGE GREEN: I mean it may anticipate more than your particular composition, with your particular compound, but I mean, it does -- it is not a huge list of additional compounds that could be put in with the rapamycin. That would be beyond the level of skill of the ordinary artisan to envision all of these in a composition with rapamycin. And isn't that the test for 102?

MR. SILVER: Right. The test for 102 is that all of the elements are identically disclosed in the reference. I think that, specifically

with respect to this pharmaceutical composition, that the specific compound isn't particularly culled out. And that would require picking from this list.

JUDGE GREEN: So we have a list of seven NMDA antagonists.

(Pause.)

JUDGE ADAMS: Anything else?

MR. MORAN: Could we have one minute?

JUDGE SCHEINER: Sure.

(Pause.)

MR. SILVER: Yes, I think that was it.

JUDGE SCHEINER: Okay, thank you.

MR. SILVER: Thank you.

Whereupon, at 10:05 a.m., the proceedings were concluded.

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